

Dear Ms Zarama:

Here is some text from a letter I wrote some years ago on the subject of non-Inventory reagents for use in exempt R&D. This is acceptable. Please feel free to contact me if you have any questions after reviewing the web site to which Clive Davies referred you. I've given your inquiry prenotice communication number 7638. Dave Schutz

Text follows:

Any new chemical substance which will be manufactured or imported in small quantities solely for research and development (R&D) in accordance with procedural and recordkeeping requirements at 40 CFR 720.36 and 720.78 is exempt from PMN requirements. For this exemption to apply, the chemical substance must either be the focus of R&D itself, or be used in R&D activity focusing on another chemical substance. **Reagents and chemical substances used in laboratories are considered as substances that fall into the latter category.** Please note that the burden of proving eligibility for the R&D exemption is entirely with the person claiming it. EPA advises those claiming the exemption to be prepared to justify their claim to EPA in adequate detail. It is your responsibility to make that determination internally.

All procedural and recordkeeping provisions of the R&D exemption at 40 CFR 720.36 and 720.78 must be maintained for the R&D exemption to be considered valid. This includes the provision at 720.36(c)(2) to notify customers in writing that the substance is to be used only for R&D purposes and to provide the notice of any health risk associated with the substance. Procedural requirements concerning new chemical substances manufactured under the §5(h)(3) R&D exemption are usefully discussed in the Federal Register of 22 April 1986, 51 FR 15096-15103. **You should consider whether these ongoing requirements impose more costs on you than you would incur through filing a Section 5 notice. Also, you should note that, as the importer, it would be you who filed the Section 5 notice, not the European manufacturer who was selling the material to you. It may be that a Section 5 notice seeking a Low Volume Exemption (under 10,000 kg per year) would serve your needs here.**

Manufacturers and processors may derive compensation from the sale of substances on which R&D will be conducted, or from the sale of substances such as laboratory reagents, chemical standards for analysis in laboratories, or intermediates to be used in the production of R&D chemicals, without being subjected to TSCA section 5(a) notification (PMN) requirements, as long as any such substances are manufactured and distributed in accordance with the procedural and recordkeeping requirements at 40 CFR 720.36 and 720.78. No substance produced under the exemption for R&D or mixture containing that substance may be sold or used for any non-exempt commercial purpose, unless the substance has completed PMN review, is granted a test market exemption, or qualifies for a low volume exemption under 40 CFR 723.50. For your import to be exempt, none of the material you import may be diverted to non-exempt purposes.

About import certification under §13 of the TSCA for R&D substances: you, as the importer, must certify that all chemical substances in your import shipment comply with all rules or orders under the TSCA and that you are not offering any chemical substance for entry in violation of the TSCA or of any applicable rule or order under the TSCA (the TSCA defines importation as the same as manufacture). This is, of course, true for both R&D and non-R&D substances. The Agency has no jurisdiction over foreign manufacture. As the importer, you are considered the liable party, for import and certification, and you need to apply a positive TSCA certification to your imported R&D substance.

An R&D substance is subject to the TSCA but exempt from PMN Inventory reporting (again, provided you follow the procedures and recordkeeping requirements found at §720.36 and §720.78). For the exact language and procedural regulations for imported chemical substances you should consult the Importers'-Exporters' Package, available from the Hotline or on our web site.